HARVARD SCHOOL OF PUBLIC HEALTH
Department of Environmental Health
Exposure, Epidemiology and Risk Program

Comment 91

June 23, 2005

Re: Request for public comment **TTB Notice No. 41**

Allergen Labeling

Further to my description of the issue of allergens in alcoholic beverages contained in my petition, I would like to further outline the issues and address the specific questions raised in the request for public comment.

1. Although milk, egg, fish, shellfish, tree nuts, peanuts, wheat, and soy account for most of the food allergy reactions, there are still a significant number of reactions to other proteins not in this list. Therefore a comprehensive ingredient listing would provide the most useful information to allergic individuals regardless of the particular allergen. If the ingredient listing is complete and complies with the FALCP Act to provide this information in common language then no additional allergen warning would be necessary.
2. I believe that one section of the labeling should be the reliable source of ingredient information. The ingredient listing should be the authoritative source of information regardless of other labeling such as that on front labels. An example is the case of artificial flavorings. A beverage may state, for example, "coconut rum" but the actual ingredients may not contain any real coconut, but rather artificial coconut flavoring. Conversely, some products may contain the allergen and not be flavored artificially. This is important information for the allergic individual and the distinction is important. Ingredient lists would make this distinction clear.
3. Declaration of processing agents is important as residuals are carried through to the finished product. While little has been written in the scientific literature on the prevalence allergic reactions to processing agents, I can attest to the fact that they do occur. I have had reactions on several occasions to egg used in the processing of wine. After a number of these allergic events I have contacted the winery and asked about the specific wine and vintage year. In every case I have confirmed the use of egg in processing. Hence it is important to include a list of allergens used in processing even though documented cases of reaction exist only as anecdotal evidence and have not yet reached the scientific literature. An indication that a particular beverage "may contain egg protein" potentially complicates the issue. It leaves the question open as to whether the allergen is or is not in the beverage. Since manufacturers control what is used in a product the onus must be on them to definitively state the contents of their products. If a substance is used in the product or it's processing, it should be listed definitively as such. It is particularly an issue if the language "may contain" is allowed to be used by manufacturers as a blanket disclosure for possible scenarios of processing aids that may or may not have been used. For example, an individual may drink several different beverages with the listing "may

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contain egg" without incident if the beverage does not really contain egg. They may mistakenly think that they are not very sensitive. Upon drinking another beverage with the same listing, but that truly contains the allergen, they could have a large exposure to the allergen and it could elicit a strong reaction. The most informative listing, useful in avoiding high-risk allergic reactions, would definitively state whether a particular allergen was used in processing of that particular batch of the beverage (eg for wines, a particular varietal and vintage year).

4. It is logical that the ingredient listing be separate from the listing of processing aids to inform the public of allergens that would be in higher concentration as ingredients than as processing aids. The listing of processing aids should be standardized and follow directly after the ingredient listing so that this information is clear and easy to find.
5. There are few studies of the minimum reactive quantities, but one study determined, based on the assumption of 100g of food consumed, that detection tests should at least have sensitivities in the 5-30 ppm range, depending on the allergen, to guarantee a 95% safety for egg, peanut and milk allergic individuals (Morisset et al 2003). However, an allergic individual can be extraordinarily sensitive to an allergen and could react at concentrations potentially below the lower limit of detection for a test used to determine residual allergen in a product. Therefore, disclosure of the fining and processing agents used is the safest for the allergic individual and the least costly approach for the manufacturer. The absolute content of the allergen need not be tested or disclosed, as the simple disclosure of the presence of an allergen would allow an allergic individual to make the an informed decision.

Morisset M, Moneret-Vautrin A, Kanny G, Guenard L, Beaudouin E, Flabbee E, Hatahet, R. 2003. Thresholds of clinical reactivity to milk, egg, peanut and sesame in immunoglobulin E-dependent allergies: evaluation by double-blind or single-blind placebo-controlled oral challenges. Clin Exp Allergy 33:1046-1051.

6. Unfortunately there is no scientific consensus on the threshold level that could be regarded as "safe" for any allergens. There may be allergen levels where typically a reaction may or may not occur, but there is a wide range of individual sensitivities. Hence the most appropriate approach is to declare the presence of allergens or their use in processing and allow the allergic individual to assess their own sensitivities.
7. I don't think it is possible to define a minimum threshold for allergens that would assure the most sensitive of individuals that a reaction will not occur. The allergic state is not a yes/no situation at any level because allergic sensitivities change over time. Individuals have heightened sensitivities in the weeks immediately following a previous allergen exposure. If thresholds were determined using data from recently exposed individuals, a lower threshold would likely be determined than that for the "average" allergic population.
8. Even if a minimum threshold for allergens were established by scientific evidence and imposed by the FDA, I think the issue of allergens in alcoholic beverages poses a significantly different case. Some of the components of alcoholic beverages can heighten the allergic response (eg increase the release of histamines). Therefore minimum threshold values established for food may not be sufficient for alcoholic beverages.

9. Any change to the labeling of alcoholic beverages will increase costs to manufacturers and distributors in the short term, but some of the proposed changes may not increase costs substantially in the long term. I believe that tests of allergen content would be prohibitively costly for a manufacturer and provide little additional benefit to an allergic individual above a declaration of the presence of an allergen as an ingredient or in processing. Overall the addition of ingredient labeling should not add significant costs to manufacturers.
10. Ingredient labeling including allergens would be a significant benefit to consumers, particularly those with food allergy. Currently, besides abstinence, the only way to determine if allergens are present in alcoholic beverages is to either contact the brewer/distiller directly for each bottle consumed, or to engage in the more usual high-risk behavior of "trial and error". The latter approach is complicated by the fact that the onset of an allergic reaction can be similar to or be obscured by the effects of alcohol (eg generalized flushing, lightheadedness). There is a very real potential for life-threatening allergic reactions when consumers are unaware of the contents of things they commonly ingest. Currently a substantial cost is incurred by the allergic public who suffer 4-6 hours of debilitating illness as a result of allergic reactions from hidden or unknown ingredients. There are also economic costs as a result of medications and emergency room visits associated with these incidents. A more appropriate approach is to require manufacturers and producers to provide ingredient and processing information. As it is in the food industry, this should be a mandatory, not voluntary, requirement to protect public health.

Furthermore, TTB has previously relied on the FDA for guidance on allergens such as in the recent temporary ruling on Lysozyme from egg for the treatment of wine (Federal Register, Vol 69 No 223 Friday November 19, 2004). In that temporary ruling it states "The FDA regulations at 21 CFR 184.1550 states that egg white lysozyme is GRAS [generally regarded as safe] when used in the production of cheese." It further states "in 1993 the ATF requested an advisory opinion from the FDA regarding the safety of the use of lysozyme in wine…." The reply was that FDA is "currently unaware of any safety or health concerns for the general population with regard to the use of lysozyme in wine. Essentially, the use in question consists of adding a chemically unmodified major protein component (lysozyme) of one common food (eggs) to another common food (wine)." However, much has been learned in the last decade regarding food allergy and the FDA is now seriously committed to careful allergen labeling through the FALCP Act. I can also attest to the fact that egg allergic individuals can react to lysozyme in cheese (I have done so on a number of occasions) and for me egg lysozyme could not and should not be "generally regarded as safe", although it may be for the majority of the population.

Sincerely,

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